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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/616,494 | 07/10/2003 | Ratan K. Chaudhuri | EMI-54 | 9716 |
| 23599 7590 02/07/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | EXAMINER ARNOLD, ERNST V | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 02/07/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/616,494 | | CHAUDHURI ET AL. | |
| | Examiner | | Art Unit | |
| | Ernst V. Arnold | | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 and 8-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/06 has been entered.

Claims 1-4, 6 and 8-35 are pending in the application.

Comment: The metes and bounds of "substantially anhydrous" are in the specification on page 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6 and 8-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal U.S. Patent No. 6,362,167 and Vatter et al. U.S. Patent No. 6,475,500.

Applicant claims an anhydrous composition comprising

(a) an antioxidant blend comprising over 40% by weight of hydrolysable tannins comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than 0.01% by weight of Rutin,

(b) a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant wherein (a) and (b) are mixed at a temperature below 60 °C.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Ghosal discloses an extract blend that comprises by weight 35-55% of Emblicanin-A and Emblicanin B; about 4-15% of Punigluconin; and about 10-30% of Pedunculagin; about 0-15% of Rutin and about 10-30% of tannoids of gallic/ellagic acid (Column 8, lines 12-20). The Examiner considers 0.001 to 0.01% Rutin within the range 0 to 15% Rutin specified by Ghosal.

The features recited in applicant's claim 3 are noted. The difference between claim 3 and Ghosal is that Ghosal does not expressly disclose 20-35 wt% Emblicanin A and 10-20 wt% Emblicanin B. Ghosal discloses a combined amount of 35-55 wt% of the two ingredients, which is sufficient to encompass the combined amounts of said

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ingredients in applicant's claim 3. Additionally, at for example, 40 wt% total of the two ingredients, as disclosed and suggested by Ghosal, equal amounts of the two ingredients would be 20 wt% each. Hence, given the variability of extract content, which would be expected by the ordinary skilled artisan in this field, the percentages of Emblicanin A and B as set forth in claim 3 would have been fairly suggested from Ghosal's teachings.

Vatter et al. disclose an anhydrous cosmetic composition that improves skin color, texture and feel which is prepared by mixing: DC9040 cross linked elastomer gel (a dimethicone gelling agent); cyclomethicone (a silicone oil); silica, titanium dioxide (a sunscreen agent), iron oxide (Ronasphere LDP); isoeicosane (permethyl 102A); alkyl methicone (DC AMS C30 wax) (a structural agent); iron oxides-silicone coated; and titanium dioxide-silicone coated (Column 30, lines 47-64 and Column 32, lines 5-6). Vatter et al. disclose that bismuth oxychloride is a suitable agent to add to the composition (Column 13, lines 9-10). Vatter et al. disclose that polyethylene glycol is a suitable humectant to add to the composition (Column 11, lines 60-61).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Ghosal does not expressly teach a composition comprising the antioxidant extract blend and a substantially anhydrous or non-aqueous liquid vehicle further comprising a sunscreensing agent or bismuth oxychloride and mixing at a temperature below 60 °C.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce an anhydrous composition comprised of the antioxidant composition of Ghosal, derived from the fruit of the *Embllica officinalis* plant containing 0-15% Rutin and the anhydrous skin lotion of Vatter et al. and mixing at a temperature below 60 °C to produce the instant invention. One having ordinary skill in the art would have been motivated to do this because Vatter et al. suggest that antioxidants can be incorporated into the compositions of their disclosure (Column 23, lines 55-67) and Ghosal suggests formulating the antioxidants into lotions and creams (column 7, lines 28-34). Mixing ingredients at room temperature is well within the ability of one of ordinary skill in the art. With respect to the choice of bismuth oxychloride having a particle size of less than 35 microns (80% within range) and a median size of 8 to 20 microns, it is deemed merely a matter of judicious selection of commercially available products, acknowledged by the applicant as Biron (LF®-2000), which is well within the purview of one of ordinary skill in the art. Bismuth oxychloride is established in the art as an inexpensive product, which exhibits a controlled pearlescent effect (See: Kaufman US 3,822,141; column 1, lines 65-67). Bismuth oxychloride is established in the art as an ingredient in anhydrous compositions (See: Brieva et al. US 6,103,250; column 5, lines 1-6 and column 11, Examples 4 and 5; and Arraudeau et al. US 4,820,510; claims 9 and 13). The improvement of skin feel is an inherent property of bismuth oxychloride

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and anyone using a product containing bismuth oxychloride would have had that benefit.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserted that the teachings of Ghosal when considered as a whole provide no motivation to use levels of Rutin with the range of 0.001 to 0.01% by weight of the composition. The Examiner cannot agree. Claim language is controlling. The disclosure of Ghosal encompasses the instantly claimed range and Applicant has not demonstrated the criticality of the instantly claimed range.

Applicant asserted that Ghosal does not teach a method of formulating an antioxidant blend at temperature below 60 C. The Examiner cannot agree. Ghosal

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formulates 3 solutions: one to test antioxidant activity which is presumed to have been conducted at room temperature (Column 4, Antioxidant activity); one with methylmethacrylate in water was heated to 35 C for about 24 hours (Column 5, polymerization of methylmethacrylate) and one to test the prevention of DNA strand scission which is presumed to have been performed at room temperature (Column 6, prevention of DNA strand scission). Thus Ghosal establishes formulating the antioxidant formulation at a temperature below 60 C. The reference of Vatter et al. is relied upon to further define the types of carriers for formulations already suggested by Ghosal at column 7, lines 28-34.

Applicant asserted that there is no motivation to combine the compounds of Ghosal with the anhydrous composition of Vatter. The Examiner cannot agree. Ghosal suggests formulations of creams and lotions without defining the exact compositions. Vatter remedies this deficiency in Ghosal by teaching cosmetic compositions that improves skin color, texture and feel.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, and 8-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 11-15 and 17-19 of U.S. Patent No. 6,649,150 in view of Vatter et al. U.S. Patent No. 6,475,500.

The 150' patent discloses a powder composition consisting essentially of by weight: 20-35% Emblicanin A, 10-20% Emblicanin B, 15-30% Pedunculagin and 3-12% Punigluconin 0.001 to 0.01% by weight of Rutin, less than about 1% flavonoids, said weight percentages having an average deviation of not more than 10% (Claim 1). The 150' patent further discloses a formulation according to claim 1 and a cosmetically or pharmaceutically acceptable carrier (Claims 5 and 17). The powder of the composition consists of essentially over 40% by weight of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 1% by weight of flavonoids (Claim 18) and the powder according to claim 18 can consist essentially of by weight 50-80% of Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and less than about 0.06% by weight of flavonoids (Claim 19). In addition, the formulation can further comprise a photoprotective agent (sunscreen) (Claim 8).

The 150' patent does not expressly disclose an anhydrous composition comprising an antioxidant comprising over 40% by weight of hydrolysable tannins

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comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant or expressly disclose the addition of bismuth oxychloride.

Vatter et al. is relied upon as described above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made modify the antioxidant composition of the 150' patent by mixing it in a non-aqueous substantially anhydrous liquid vehicle taught by Vatter et al. to produce the instantly claimed invention. One of ordinary skill in the art would have been motivated to do so because the 150' patent suggests that the composition can be formulated with a cosmetically or pharmaceutically acceptable carrier (Claim 5). One of ordinary skill in the art would have found the disclosure of Vatter et al. and produced the instant invention.

Response to arguments:

Applicant asserted that the scope of US 6,649,150 does not overlap with the scope of the amended claim 1. The Examiner cannot agree. It remains obvious one of ordinary skill in the art to mix components at room temperature, which is below 60 C.

Double Patenting

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 10, and 15-20 of copending Application No. 10/501,752. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the

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instant invention embraces or is embraced by the subject matter of the co-pending application. One of ordinary skill in the art would recognize that mixing at room temperature of the extract disclosed in 10/501,752 when formulated as a composition with the same percent by weight amounts of each component, claims 1-3, with a pharmaceutically acceptable carrier as described in claim 10 as obvious with respect to the instant invention. The co-pending application also recites the less than 0.01% by weight Rutin limitation.

Claims 1-4, 6, 8-24 and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5-12 of copending Application No. 10/534,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant invention embraces or is embraced by the subject matter of the co-pending application. Copending claims 1-3 and 11 embrace instant claims 1-4 and 6. Copending claims 5-7 recite anhydrous compositions and structural and gelling agents which reads on instant claims 8-17. Copending claim 8 embraces sunscreens which reads on instant claims 18-24. Copending claims 9 and 12 recite bismuth oxychloride which reads on instant claims 25-34. Copending claim 10 method of producing an anhydrous composition reads on instant claim 35 drawn to a method of producing an anhydrous composition. One of ordinary skill in the art would have recognized the obvious variation of the instant claims and the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

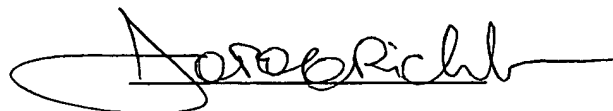
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning and a horizontal line extending to the right.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600